

Liza M. Walsh  
Rukhsanah L. Singh  
CONNELL FOLEY LLP  
85 Livingston Avenue  
Roseland, New Jersey 07068  
973-535-0500  
973-535-9217 (fax)  
lwalsh@connellfoley.com

Charles A. Weiss  
HOLLAND & KNIGHT LLP  
31 West 52nd Street  
New York, NY 10019  
212-513-3551  
212-385-9010 (fax)  
charles.weiss@hklaw.com

*Attorneys for Defendant  
Actavis Laboratories FL, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

VIVUS, INC.,

Plaintiff,

v.

ACTAVIS LABORATORIES FL, INC.

Defendant.

Civil Action No. 14-cv-03786-FSH-MAH

**ANSWER AND COUNTERCLAIM OF  
DEFENDANT ACTAVIS LABORATORIES FL, INC.**

Defendant Actavis Laboratories FL, Inc. (“AF” or “Defendant”), by way of Answer to the June 12, 2014 Complaint in the above captioned case (“Complaint”), alleges and say:

**Nature of the Action**

1. To the extent that Paragraph 1 of the Complaint states conclusions of law, AF states that no response is required. To the extent that a response is required, AF admits that Plaintiff purports to state claims that arise under the patent laws of the United States. Admitted that AF filed an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of QSYMIA before the stated expiration of United States Patent Nos. 7,056,890 (the ’890 patent”), 7,553,818 (the ’818 patent”), 7,659,256 (the ’256 patent”), 7,674,776 (“the ’776 patent”), 8,580, 298 (“the ’298 patent”), and 8,580,299 (“the ’299 patent”) (collectively, “the patents-in-suit”). AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 of the Complaint.

**The Parties**

2. AF is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint.

3. Admitted that AF is a corporation organized under the laws of the State of Florida with a place of business at 4955 Orange Drive, Davie, Florida 33314. Otherwise denied.

4. Admitted that AF develops generic drugs. Otherwise denied.

5. The allegations in Paragraph 5 of the Complaint are directed to an entity no longer a party to this suit pursuant to the August 5, 2014 Stipulation and Order Dismissing Without Prejudice Defendants Actavis, Inc. and Actavis plc and Amending Caption to Reflect Same, D.I. 13 in Civil Action No. 14-3786 (FSH)(MAH) (“Stipulation of Dismissal”), and, therefore, AF states that no response is required.

6. Admitted.

7. The allegations in Paragraph 7 of the Complaint are directed to an entity no longer a party to this suit pursuant to the Stipulation of Dismissal, and, therefore, AF states that no response is required.

8. The allegations in Paragraph 8 of the Complaint are directed to an entity no longer a party to this suit pursuant to the Stipulation of Dismissal, and, therefore, AF states that no response is required.

9. To the extent that the allegations in Paragraph 9 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

10. Admitted that Plaintiff purports to collectively refer to Actavis FL, Inc., Actavis, Inc., and Actavis plc as “Actavis.”

#### **Jurisdiction and Venue**

11. To the extent that Paragraph 11 of the Complaint states conclusions of law, AF states that no response is required. To the extent that a response is required, AF admits that Plaintiff purports to state claims that arise under the patent laws of the United States, and admits that the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 for the present case.

12. To the extent that Paragraph 12 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF states that it does not contest personal jurisdiction in New Jersey for purposes of this case.

13. To the extent that Paragraph 13 of the Complaint states conclusions of law, AF states that no response is required. To the extent that a response is required, AF states that it will not contest venue for purposes of this case.

**The Patent-in-Suit**

14. AF admits that the '890 patent is entitled "Combination therapy for effecting weight loss and treating obesity," the face of the '890 patent recites an issue date of June 6, 2006, and that a copy of the '890 patent was attached to the Complaint at Exhibit A. AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14 of the Complaint. Otherwise denied.

15. AF admits that the '818 patent is entitled "Combination therapy for effecting weight loss and treating obesity," the face of the '818 patent recites an issue date of June 30, 2009, and that a copy of the '818 patent was attached to the Complaint at Exhibit B. AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 of the Complaint. Otherwise denied.

16. AF admits that the '256 patent is entitled "Combination therapy for effecting weight loss and treating obesity," the face of the '256 patent recites an issue date of February 9, 2010, and that a copy of the '256 patent was attached to the Complaint at Exhibit C. AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 16 of the Complaint. Otherwise denied.

17. AF admits that the '776 patent is entitled "Combination therapy for effecting weight loss and treating obesity," the face of the '776 patent recites an issue date of March 9, 2010, and that a copy of the '776 patent was attached to the Complaint at Exhibit D. AF is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17 of the Complaint. Otherwise denied.

18. AF admits that the '298 patent is entitled "Low dose topiramate/phentermine composition and methods of use thereof," the face of the '298 patent recites an issue date of November 12, 2013, and that a copy of the '298 patent was attached to the Complaint at Exhibit E. AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18 of the Complaint. Otherwise denied.

19. AF admits that the '299 patent is entitled "Escalating dosing regimen for effecting weight loss and treating obesity," the face of the '299 patent recites an issue date of November 12, 2013, and that a copy of the '299 patent was attached to the Complaint at Exhibit F. AF is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19 of the Complaint. Otherwise denied.

#### **The QSYMIA Drug Products**

20. To the extent that Paragraph 20 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of the Complaint. Otherwise, denied.

21. Admitted.

#### **Acts [Allegedly] Giving Rise to This Suit**

22. To the extent that Paragraph 22 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is

required from AF, AF admits that it filed ANDA No. 204982 for 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg capsules of phentermine and topiramate extended-release.

23. To the extent that Paragraph 23 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF state that the pertinent statute speaks for itself, but admitted that AF sent the cited certification to the FDA. Otherwise denied.

24. To the extent that Paragraph 24 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF state that the pertinent statute speaks for itself, but admitted that AF sent the cited letter. Otherwise denied.

### **Count I**

25. AF repeats its responses to Paragraphs 1 through 24 of the Complaint as if set forth at length herein.

26. To the extent that the allegations in Paragraph 26 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

27. To the extent that Paragraph 27 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF admits that the Complaint purports to allege that there is a justiciable

controversy between Plaintiff and AF as to the infringement of the '890 patent. Otherwise denied.

28. To the extent that the allegations in Paragraph 28 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

29. To the extent that the allegations in Paragraph 29 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

30. To the extent that the allegations in Paragraph 30 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

31. To the extent that the allegations in Paragraph 31 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

32. Denied.

33. Denied.

### **Count II**

34. AF repeats its responses to Paragraphs 1 through 33 of the Complaint as if set forth at length herein.

35. To the extent that the allegations in Paragraph 35 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

36. To the extent that Paragraph 36 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF admits that the Complaint purports to allege that there is a justiciable controversy between Plaintiff and AF as to the infringement of the '818 patent. Otherwise denied.

37. To the extent that the allegations in Paragraph 37 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

38. To the extent that the allegations in Paragraph 38 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

39. To the extent that the allegations in Paragraph 39 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

40. To the extent that the allegations in Paragraph 40 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

41. Denied.

42. Denied.

### **Count III**

43. AF repeats its responses to Paragraphs 1 through 42 of the Complaint as if set forth at length herein.



44. To the extent that the allegations in Paragraph 44 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

45. To the extent that Paragraph 45 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required, AF admits that the Complaint purports to allege that there is a justiciable controversy between Plaintiff and AF as to the infringement of the '256 patent. Otherwise denied.

46. To the extent that the allegations in Paragraph 46 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

47. To the extent that the allegations in Paragraph 47 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

48. To the extent that the allegations in Paragraph 48 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

49. To the extent that the allegations in Paragraph 49 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

50. Denied.

51. Denied.

**Count IV**

52. AF repeats its responses to Paragraphs 1 through 51 of the Complaint as if set forth at length herein.

53. To the extent that the allegations in Paragraph 53 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

54. To the extent that Paragraph 54 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF admits that the Complaint purports to allege that there is a justiciable controversy between plaintiff and AF as to the infringement of the '776 patent. Otherwise denied.

55. To the extent that the allegations in Paragraph 55 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

56. To the extent that the allegations in Paragraph 56 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

57. To the extent that the allegations in Paragraph 57 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

58. To the extent that the allegations in Paragraph 58 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

59. Denied.

60. Denied.

### **Count V**

61. AF repeats its responses to Paragraphs 1 through 60 of the Complaint as if set forth at length herein.

62. To the extent that the allegations in Paragraph 62 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

63. To the extent that Paragraph 63 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF admits that the Complaint purports to allege that there is a justiciable controversy between plaintiff and AF as to the infringement of the '298 patent. Otherwise denied.

64. To the extent that the allegations in Paragraph 64 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

65. To the extent that the allegations in Paragraph 65 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

66. To the extent that the allegations in Paragraph 66 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

67. To the extent that the allegations in Paragraph 67 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

68. Denied.

69. Denied.

### **Count VI**

70. AF repeats its responses to Paragraphs 1 through 69 of the Complaint as if set forth at length herein.

71. To the extent that the allegations in Paragraph 71 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

72. To the extent that Paragraph 72 of the Complaint states conclusions of law or makes allegations against other defendants or against entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, AF admits that the Complaint purports to allege that there is a justiciable controversy between plaintiff and AF as to the infringement of the '299 patent. Otherwise denied.

73. To the extent that the allegations in Paragraph 73 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

74. To the extent that the allegations in Paragraph 74 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

75. To the extent that the allegations in Paragraph 75 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

76. To the extent that the allegations in Paragraph 76 of the Complaint are directed to entities no longer parties to this suit pursuant to the Stipulation of Dismissal, AF states that no response is required. To the extent that a response is required from AF, denied.

77. Denied.

78. Denied.

### **DEFENSES**

79. The Complaint fails to state a claim upon which relief may be granted.

80. The manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 204982 would not infringe any valid or enforceable claim of the patents-in-suit.

81. The claims of the patents-in-suit insofar as they may relate to that certain proposed product that is the subject of ANDA No. 204982 are invalid for failure to comply with one or more sections of Title 35, United States Code, including, but not limited to, sections 101, 102, 103, and 112.

82. AF reserves the right to assert additional defenses in the event that discovery or other analyses indicates that additional defenses are appropriate.

### **COUNTERCLAIMS**

Counterclaimant Actavis Laboratories FL, Inc. (“Counterclaimant/Defendant” or “AF”) asserts the following counterclaims against VIVUS, Inc. (“Counterclaim Defendant/Plaintiff” or “VIVUS”) that United States Patent Nos. 7,056,890 (the ’890 patent”), 7,553,818 (the ’818 patent”), 7,659,256 (the ’256 patent”), 7,674,776 (“the ’776 patent”), 8,580, 298 (“the ’298 patent”), and 8,580,299 (“the ’299 patent”) (collectively, “the patents-in-suit”) are not infringed by the proposed product that is the subject of Abbreviated New Drug Application (“ANDA”) No. 204982, and/or are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

### **THE PARTIES**

83. Counterclaimant/Defendant AF is a corporation organized under the laws of the State of Florida with a place of business at 4955 Orange Drive, Davie, Florida 33314.

84. On information and belief, and based on Counterclaim Defendant/Plaintiff VIVUS’s allegations in its Complaint, Counterclaim Defendant/Plaintiff VIVUS is a corporation organized and existing under the laws of Delaware, having its principal place of business at 351 E. Evelyn Avenue, Mountain View, California 94041.

### **NATURE OF THE ACTION**

85. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. AF seeks declarations that the patents-in-suit are not infringed by the proposed products that are the subject of AF’s ANDA No. 204982, and/or are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

### **JURISDICTION AND VENUE**

86. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy between Counterclaimant/Defendant AF and Counterclaim Defendant/Plaintiff VIVUS, arising under the patent laws of the United States, 35 U.S.C. § 1 et seq. This Court has original jurisdiction over the subject matter of these claims under at least 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

87. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff based on, *inter alia*, Counterclaim Defendant's/Plaintiff's filing of this lawsuit in this jurisdiction.

88. Venue is proper in this judicial district.

### **BACKGROUND**

89. The '890 patent, on its face, is entitled "Combination therapy for effecting weight loss and treating obesity," and lists its date of issue as June 6, 2006.

90. The '818 patent, on its face, is entitled "Combination therapy for effecting weight loss and treating obesity," and lists its date of issue as June 30, 2009.

91. The '256 patent, on its face, is entitled "Combination therapy for effecting weight loss and treating obesity," and lists its date of issue as February 9, 2010.

92. The '776 patent, on its face, is entitled "Combination therapy for effecting weight loss and treating obesity," and lists its date of issue as March 9, 2010.

93. The '298 patent, on its face, is entitled "Low dose topiramate/phentermine composition and methods of use thereof," and lists its date of issue as November 12, 2013.

94. The '299 patent, on its face, is entitled "Escalating dosing regimen for effecting weight loss and treating obesity," and lists its date of issue as November 12, 2013.

95. On information and belief, and based on Counterclaim Defendant's/ Plaintiff's allegations in its Complaint, the patents-in-suit are owned by VIVUS, Inc.

96. On information and belief, and based on Counterclaim Defendant's/Plaintiff's allegations in its Complaint, VIVUS, Inc. is the holder of New Drug Application ("NDA") No. 022580, which was approved by the FDA for the manufacture and sale of phentermine and topiramate extended-release capsules, 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg, which Counterclaim Defendant/Plaintiff markets under the name QSYMIA.

97. On information and belief, the United States Food and Drug Administration ("FDA") approved NDA No. 0225802 on July 17, 2012.

98. AF submitted to the FDA ANDA No. 204982 for phentermine and topiramate extended-release capsules, 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg, before the stated expiration of the patents-in-suit. AF made a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the patents-in-suit would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the proposed product that is the subject of ANDA No. 204982 (the "ANDA Product").

99. On June 12, 2014, Counterclaim Defendant/Plaintiff filed their Complaint alleging infringement by AF, Actavis Inc. ("Actavis"), and Actavis plc ("PLC") of the patents-in-suit.

**COUNT I**  
**(Declaration of Invalidity of the '890 Patent)**

100. AF incorporates by reference Paragraphs 83 through 99 of its Counterclaims as if fully set forth herein.



101. The claims of the '890 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

102. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '890 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

103. AF is entitled to a judicial declaration that the '890 patent is invalid.

**COUNT II**  
**(Declaration of Noninfringement of the '890 Patent)**

104. AF incorporates by reference Paragraphs 83 through 103 of its Counterclaims as if fully set forth herein.

105. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '890 patent.

106. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '890 patent under the doctrine of equivalents.

107. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '890 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

108. AF is entitled to a judicial declaration that the '890 patent is not infringed.

**COUNT III**  
**(Declaration of Invalidity of the '818 Patent)**

109. AF incorporates by reference Paragraphs 83 through 108 of its Counterclaims as if fully set forth herein.

110. The claims of the '818 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

111. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '818 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

112. AF is entitled to a judicial declaration that the '818 patent is invalid.

**COUNT IV**  
**(Declaration of Noninfringement of the '818 Patent)**

113. AF incorporates by reference Paragraphs 83 through 112 of its Counterclaims as if fully set forth herein.

114. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '818 patent.

115. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '818 patent under the doctrine of equivalents.

116. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the

ANDA Product of the '818 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

117. AF is entitled to a judicial declaration that the '818 patent is not infringed.

**COUNT V**  
**(Declaration of Invalidity of the '256 Patent)**

118. AF incorporates by reference Paragraphs 83 through 117 of its Counterclaims as if fully set forth herein.

119. The claims of the '256 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

120. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '256 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

121. AF is entitled to a judicial declaration that the '256 patent is invalid.

**COUNT VI**  
**(Declaration of Noninfringement of the '256 Patent)**

122. AF incorporates by reference Paragraphs 83 through 121 of its Counterclaims as if fully set forth herein.

123. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '256 patent.

124. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute

to the infringement of any valid or enforceable claim of the '256 patent under the doctrine of equivalents.

125. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '256 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

126. AF is entitled to a judicial declaration that the '256 patent is not infringed.

**COUNT VII**  
**(Declaration of Invalidity of the '776 Patent)**

127. AF incorporates by reference Paragraphs 83 through 126 of its Counterclaims as if fully set forth herein.

128. The claims of the '776 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

129. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '776 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

130. AF is entitled to a judicial declaration that the '776 patent is invalid.

**COUNT VIII**  
**(Declaration of Noninfringement of the '776 Patent)**

131. AF incorporates by reference Paragraphs 83 through 130 of its Counterclaims as if fully set forth herein.

132. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '776 patent.

133. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '776 patent under the doctrine of equivalents.

134. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '776 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

135. AF is entitled to a judicial declaration that the '776 patent is not infringed.

**COUNT IX**  
**(Declaration of Invalidity of the '298 Patent)**

136. AF incorporates by reference Paragraphs 83 through 135 of its Counterclaims as if fully set forth herein.

137. The claims of the '298 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

138. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

139. AF is entitled to a judicial declaration that the '298 patent is invalid.

**COUNT X**  
**(Declaration of Noninfringement of the '298 Patent)**

140. AF incorporates by reference Paragraphs 83 through 139 of its Counterclaims as if fully set forth herein.

141. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '298 patent.

142. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '298 patent under the doctrine of equivalents.

143. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '298 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

144. AF is entitled to a judicial declaration that the '298 patent is not infringed.

**COUNT XI**  
**(Declaration of Invalidity of the '299 Patent)**

145. AF incorporates by reference Paragraphs 83 through 144 of its Counterclaims as if fully set forth herein.

146. The claims of the '299 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 et seq.

147. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the validity of the '299 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

148. AF is entitled to a judicial declaration that the '299 patent is invalid.

## **COUNT XII**

### **(Declaration of Noninfringement of the '299 Patent)**

149. AF incorporates by reference Paragraphs 83 through 148 of its Counterclaims as if fully set forth herein.

150. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not literally infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '299 patent.

151. The manufacture, use, sale, offer for sale, and/or importation into the United States of the ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '299 patent under the doctrine of equivalents.

152. A definite and concrete, real and substantial, justiciable controversy exists between AF and Counterclaim Defendant/Plaintiff concerning the alleged infringement by the ANDA Product of the '299 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

153. AF is entitled to a judicial declaration that the '299 patent is not infringed.

**PRAYER FOR RELIEF**

**WHEREFORE**, Defendant AF demands judgment against Counterclaim Defendant/Plaintiff:

- A. Dismissing the Complaint with prejudice;
- B. Declaring that the manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 204982 does not infringe any valid claim of the patents-in-suit;
- C. Declaring that the claims of the patents-in-suit, insofar as they may relate to that certain proposed product that is the subject of ANDA No. 204982 are invalid;
- D. Finding that this case is exceptional under 35 U.S.C. § 285;
- F. Enjoining Plaintiff, its officers, agents, employees, representatives, counsel, and all persons in active concert or participation with Plaintiff, directly or indirectly, from threatening or charging infringement of, or instituting or maintaining any action for infringement of the patents-in-suit on account of the manufacture, use, offer for sale, sale, and/or importation of that certain proposed product that is the subject of ANDA No. 204982;
- G. Awarding attorneys' fees, expenses, and costs of suit; and
- H. Awarding such other and further relief as may be appropriate.

CONNELL & FOLEY LLP  
HOLLAND & KNIGHT LLP

*Attorneys for Defendant  
Actavis Laboratories FL, Inc.*

By: s/Liza M. Walsh  
LIZA M. WALSH

DATED: September 2, 2014



**CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

I hereby certify that the matter in controversy is not the subject of another pending action in any court or arbitration forum, nor are any such actions contemplated. I further certify that there are no parties of whom I am presently aware who should be joined in this action.

s/Liza M. Walsh

LIZA M. WALSH

DATED: September 2, 2014

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Defendant Actavis Laboratories FL, Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

*s/Liza M. Walsh*  
LIZA M. WALSH

DATED: September 2, 2014